



January 1997

Issues Surrounding the Patenting of Medical Procedures

Linda Judge

Follow this and additional works at: <http://digitalcommons.law.scu.edu/chtlj>



Part of the [Law Commons](#)

Recommended Citation

Linda Judge, *Issues Surrounding the Patenting of Medical Procedures*, 13 SANTA CLARA HIGH TECH. L.J. 181 (1997).
Available at: <http://digitalcommons.law.scu.edu/chtlj/vol13/iss1/5>

This Comment is brought to you for free and open access by the Journals at Santa Clara Law Digital Commons. It has been accepted for inclusion in Santa Clara High Technology Law Journal by an authorized administrator of Santa Clara Law Digital Commons. For more information, please contact sculawlibrarian@gmail.com.

COMMENTS

ISSUES SURROUNDING THE PATENTING OF MEDICAL PROCEDURES*

Linda Rabin Judge†

TABLE OF CONTENTS

I. Introduction.....	181
II. Patent Law's Impact on Technological Innovation	183
III. Historical Treatment of Medical Procedure Patents.....	187
IV. Medical and Surgical Procedures Patents in Other Coun- tries.....	189
V. Current Legislation Regarding Medical Procedure Patents...	190
VI. Lawsuits Involving Medical Procedure Patents.....	196
VII. Ethical Concerns Surrounding the Patenting of Medical Procedures.....	202
VIII. Incentives for Awarding Proprietary Rights to Medical Procedures.....	203
IX. Potential Impact on the Biotechnology Industry	208
X. Proposed Solutions to the Debate Surrounding Patenting of Medical and Surgical Procedures	210
XI. Conclusion	211

I. INTRODUCTION

The patenting of medical and surgical procedures has become a common practice with numerous patent applications filed on a weekly basis.¹ This trend has led to current legislation before the

* Copyright © 1996 Linda Rabin Judge.

† B.S. Chemistry & Biology, Sonoma State University; M.S. Environmental Chemistry, University of California at Berkeley; J.D. Santa Clara University School of Law (expected) 1997.

1. The Patent and Trademark Office issues approximately fifteen medical procedure patents each week. See *Patents Seem Fatal for Medical Ethics*, WIS. ST. J., Aug. 28, 1995, at

House and Senate aimed at minimizing or eliminating the practice.² Some medical organizations have deemed the practice of patenting medical and surgical procedures unethical.³ In 1994, the American Medical Association House of Delegates passed a resolution condemning the practice.⁴ In sharp contrast, the patenting of medical procedures was declared essential to the future of scientific innovation by members of the biotechnology industry.⁵

The controversy has been highlighted by a recent lawsuit filed by Dr. Samuel Pallin. In the lawsuit, Dr. Pallin alleged that another physician infringed his patent⁶ on a surgical procedure used to perform cataract surgery without sutures.⁷ Dr. Pallin attempted to charge those who used his patented procedure⁸ (which was widely used⁹) royalties. The outcome of the Pallin lawsuit will influence the future allowance and enforcement of medical method patents. If such patents are allowed, patients and insurance companies will face significant increases in health care costs.¹⁰

This comment reviews the current legislation and issues surrounding the role of the legislature in setting forth a solution to the dilemma regarding patenting of medical procedures. The potential

7A; see also Wendy W. Yang, *Patent Policy and Medical Patents: Case for Statutory Exclusion from Patentability*, 1 B.U. J. SCI. & TECH. L. 5 (1995).

2. *Do Patents Belong in Traditional Medicine?: Congress Considering Bills that Eliminate Protection*, LEGAL INTELLIGENCER, Nov. 2, 1995, at 9 [hereinafter *Do Patents Belong*]; see also *Medical Procedures Innovation and Affordability Act*, H.R. 1127, 104th Cong. (1995) (introduced by surgeon Representative Greg Ganske (R-Iowa) and Ron Wyden (D-Ore)); see also *Medical Procedures Innovation and Affordability Act*, S. 1334, 104th Cong. (1995) (introduced by physician Senator Bill Frist (R-Tenn)).

3. Such medical organizations include the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, the American Urological Association and the American Association of Medical Colleges. See, e. g., *Agency Opposes Bills to Create Patent Exception for Medical Procedures*, BNA HEALTH CARE DAILY, Oct. 20, 1995 [hereinafter *Agency Opposes Bills*].

4. Susan Hershberg Adelman, *An Earful About Why Lawyers Support Process Patents*, 38 A. MED. NEWS 34, 35 (1995); see also *Medical Procedures Innovation and Affordability Act: Hearings on H.R. 1127 Before the Subcommittee on Courts and Intellectual Property Committee of the House Judiciary Committee*, 104th Cong. (Oct. 19, 1995) [hereinafter *Hearings*] (testimony of Carlos J. Moorhead, Chairman, House Judiciary Courts and Intellectual Property Pending Legislation).

5. *Agency Opposes Bills*, *supra* note 3.

6. U.S. Patent No. 5,080,111.

7. *Pallin v. Singer*, No. 93-202, 1995 U.S. Dist. LEXIS 20824 (D. Vt. May 1, 1995).

8. Ron Stodghill II, *First, Do No Harm. Then, Get a Patent*, BUS. WK., July 24, 1995, at 86.

9. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery stating that at least 200 surgeons use Dr. Pallin's technique or variations thereof).

10. Stodghill, *supra* note 8.

positive and negative impacts of a ban on medical and surgical procedure patents and the effect such a restriction could have on the medical community are discussed. The issue is analyzed from the perspective of representatives of the medical community, the Patent and Trademark Office (PTO), and the pharmaceutical and biotechnology industries.

The ethical and economic issues surrounding patenting of medical procedures should not be controlled by legislative action. In the discussion that follows, the channels which already exist to allow patents on medical procedures, where appropriate, will be reviewed. In addition, a proposal for addressing the controversy regarding patenting of medical procedures through the PTO, the courts,¹¹ and by way of industry policy will be presented.

II. PATENT LAW'S IMPACT ON TECHNOLOGICAL INNOVATION

Traditional patent law has provided protection for inventions in applied technology, but not basic scientific research.¹² Section 101 of Title 35 of the United States Code (U.S.C.) provides in part that "whoever invents or discovers any new and useful process, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."¹³ The focus on applied technology is derived in part from the language of the Constitution, which authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹⁴

There are essentially three levels of patent law: the Constitutional grant of authority for Congress to create the patent laws,¹⁵ the Congressional legislation,¹⁶ and the interpretive case law.¹⁷ The

11. In 1982, Congress created the United States Court of Appeals for the Federal Circuit (CAFC) which serves as the only Federal Appellate court for patent cases. The CAFC has standardized many areas of patent law. See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.

12. Robert P. Merges, *Commercial Success and Patent Standards, Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 810 (1988).

13. 35 U.S.C. § 101 (1988) (in 1952 the word "art" was replaced by "process" in the revised statute thereby clarifying that processes are patentable subject matter).

14. U.S. CONST. art. I, § 8, cl. 8.

15. *Id.*

16. Once approved a statute regulating medical procedure patents will be codified under Title 35 of the U.S. Code.

17. See 1 DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT, § 1.03 [3], at 1-70 (1996).

Court has stated that the promotion of science and the arts is the object of patent protection and the reward given to inventors is secondary and merely a means to that end.¹⁸

The Constitution does not elaborate on what is meant by *inventors* or *discoveries*.¹⁹ The term *inventorship* has no precise definition, and no clarification on this subject has been provided by the Supreme Court or the patent statutes.²⁰ An invention is the practical manifestation of an inventor's ideas²¹ and is more than a concept. Under common law, inventorship refers to the process of conception and reduction to practice of a patentable invention.²² An invention should be distinguished from an innovation which is the functional or *debugged* version of an invention and which does not rise to a level deserving patent protection.²³

Patent law expressly requires an inventor to disclose both the invention and the best known mode of practicing it, in order to "enable any person skilled in the art to make and use" the claimed discoveries.²⁴ Patent law also requires inventors to demonstrate the utility of their inventions and excludes protection for scientific principles or ideas.²⁵ The grant of a patent is a powerful tool which gives the owner the right to exclude others from making, using, or selling an invention in the United States for a period of 20 years beginning when the patent application is filed. At the end of the 20 year period, the invention becomes available to the public.²⁶ A patent grant is initiated when the inventor files a patent application. In the application the invention must be described with sufficient detail such that one skilled in the applicable art could practice the invention.²⁷ The in-

18. *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942).

19. U.S. CONST. art. I, § 8, cl. 8.

20. *Hearings, supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

21. *Merges, supra* note 12, at 807, 808.

22. *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

23. *Merges, supra* note 12, at 807.

24. 35 U.S.C. § 112 (1988).

25. J. H. Reichman, *Computer Programs As Applied Scientific Know-How: Implications of Copyright Protection for Commercialized University Research*, 42 VAND. L. REV. 639, 649 (1989).

26. 35 U.S.C.A. § 154 (West Supp. 1996):

Such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

27. 35 U.S.C. § 112 (1988).

vention *claimed* must meet the statutory requirements of novelty, utility, and nonobviousness.²⁸ To be novel, an invention must be distinguished from the existing technology in the relevant field. Utility requires that the invention be useful and the nonobviousness requirement is met by demonstrating that the invention would not have been easily conceived by one with an ordinary level of skill in the field to which it pertains.²⁹

Within a given patent application, the *claim* describes the scope of the invention and is evaluated by the PTO which determines patentability and delineates the property rights encompassed by the patent.³⁰ The PTO examines the patent application and has the authority to grant or deny a patent. Once issued, a patent is presumed valid and subsequent challenges to validity generally occur in the context of an infringement action in the Federal Court System where the alleged infringer asserts a defense of patent invalidity.³¹ During the *ex parte* process of evaluating the merits of a patent application, the patentee has a duty of complete candor relative to communications with the PTO, and failure to satisfy this requirement can result in a loss of rights to the patent.³² The disclosure requirements parallel scientific norms by demanding that patent applicants, like publishing scientists, describe their inventions to the public and supply appropriate and sufficient information and materials to show that they have in fact achieved what they claim.³³

Published patents may be used as a source of technical information. The purpose underlying the patent statutes is to promote innovation by offering a right of exclusion for a limited period as an incentive to inventors to risk the costs of time and materials which may

28. 35 U.S.C. §§ 101-103 (1988).

29. A patent may not be obtained on a novel advancement in technology unless the subject matter sought to be patented and the prior art can be compared and the subject matter of the patent as a whole would not have been obvious to one with ordinary skill in the art to which the subject matter pertains. The modern interpretation of nonobviousness is based on a three part test supplied by the court in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In a nonobviousness determination, the judge is required to determine the state of the prior art before the current invention, evaluate what constitutes ordinary level of skill in the inventor's field and determine if the difference between the current invention and the prior art should have been obvious. This test along with secondary factors such as unfulfilled need, failure of others in the past and commercial success contribute to the nonobviousness determination; see 35 U.S.C. §§ 101-103 (1988).

30. 35 U.S.C. § 112 (1988).

31. 35 U.S.C. § 282 (1988).

32. 35 U.S.C. § 115 (1988).

33. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 207 (1987).

be required to create a patentable invention. However, patent law may operate to delay the dissemination of knowledge to other researchers and practitioners. Because of this delay, the patent system threatens the interests of the scientific and medical communities in the free use and extension of new discoveries.³⁴

It is generally accepted that the patent system was designed to serve the public interest by creating incentives for scientific innovation.³⁵ Such incentives are especially important in research intensive fields like the pharmaceutical industry, where inventions do not occur without significant investment of time and resources.³⁶ The conventional reward structure in science and medicine motivates inventors to make contributions to the scientific and medical communities in order to gain recognition for the progress they have made.³⁷ Once an inventor has filed a patent application, sharing research results or technical innovations does not interfere with patent protection for those inventions already claimed.³⁸ However, dissemination of scientific results or techniques allows general access to the information which is described and may help competitors make future discoveries. Therefore, patent applicants who are uncertain as to the patentability of their inventions may choose to defer discussion of their results until a patent is actually issued because dissemination of such information forfeits secrecy protection without any assurance of obtaining patent rights.³⁹ Once a patent has been secured by the inventor, those who make, use, or sell the patented invention must first obtain a license or they may be held liable for patent infringement.⁴⁰

As discussed above, the U. S. patent system has several levels of controls on issuance and testing of the patentability of an invention. The process of patent approval is *ex parte* and nonadversarial. In addition, patent applications are kept secret until the respective patent issues. In the course of this process, there is minimal opportunity for a challenge to patentability except those challenges raised by the PTO. Therefore, it is important that patent law provides two significant checks on the issuance of each patent. First, inventors are re-

34. *Id.* at 177.

35. Evan Ackiron, *Patents Critical for Pharmaceuticals, the AZT Case*, 17 AM. J. L. & MED. 145, 149 (1991).

36. *Id.*

37. Eisenberg, *supra* note 33, at 183, n24.

38. Patent applications are kept secret until a patent issues. 35 U.S.C.A. § 122 (West Supp. 1995).

39. Eisenberg, *supra* note 33, at 216-17.

40. 35 U.S.C. § 271 (1988).

quired to be absolutely candid when dealing with the PTO which obligates disclosure of any material information.⁴¹ Second, although third parties may not intervene in the process of patent approval, they may test the validity of a patent in the context of an infringement action in the federal court system.⁴² These controls go a long way toward providing adequate insurance that patents will not be issued and enforced for medical procedures when it is not appropriate to do so.

III. HISTORICAL TREATMENT OF MEDICAL PROCEDURE PATENTS

Historically, the medical profession and the courts have been hostile to medical process patents.⁴³ There has been a general notion that medical and surgical procedures are not patentable as processes.⁴⁴ Internal PTO decisions have recently reversed a trend which existed since an 1883 decision⁴⁵ where the Commissioner of Patents stated that "the methods or modes of treatment of physicians of certain diseases are not patentable."⁴⁶ In a 1952 decision,⁴⁷ the Patent Office Board of Appeals reversed the long existing trend of not allowing medical procedure patents. They focused on the utility of a new method for injecting a medication with a pressure jet in their allowance of the patent claim. This ruling opened the door for medical procedure patents.⁴⁸ Process patents have traditionally been used to secure proprietary rights in the health care field; patent protection of medical and diagnostic procedures have been far less common.⁴⁹ In

41. A breach of this duty may result in the patent being declared invalid or denial of relief against an alleged infringer. Duty to Disclose Information Material to Patentability, 37 C.F.R. § 1.56 (1996).

42. *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 350 (1971) (if an accused infringer overcomes the presumption of validity, there is no liability for making, using or selling the invention and furthermore, once a patent has been invalidated in one proceeding, the patentee cannot bring subsequent infringement actions).

43. Yang, *supra* note 1, at 5, n12.

44. CHISUM, *supra* note 17, § 1.03[3], at 1-70.

45. Yang, *supra* note 1, at 5, n18.

46. See CHISUM, *supra* note 17, § 1.03[3], at 1-70.

47. See *Becton-Dickinson & Co. v. Robert P. Scherer*, 106 F. Supp. 665 (E.D. Mich. 1952) (this case stands for the proposition that processes are patentable even if they consist of "medical or surgical methods" which involve treatment of the human body).

48. Following submission of a patent application, the PTO evaluates patentability in an ex parte procedure where a patent examiner who represents the PTO interacts with the patentee. If the patent application is denied, the patentee may appeal to the Patent Office Board of Appeals which has the authority to reverse decisions of the patent examiners. See *Hearings*, *supra* note 4 (testimony of William D. Noonan, M.D., physician and patent attorney, Klarquist, Sparkman, Campbell, Leigh & Whinston).

49. *Bill Would Limit Issuance of Patents on Medical Procedures*, BNA PAT., TRADEMARK & COPYRIGHT L. DAILY, Mar. 15, 1995, available in LEXIS, BNA Library,

addition, patents on medical and diagnostic procedures have rarely been enforced.⁵⁰ Patents obtained by researchers and physicians on medical procedures have been used mainly to claim credit for inventions without the expectation of financial reward.⁵¹

The historical lack of inclination to secure or enforce patents in the medical field and the rarity of litigation is partially based on the premise that it is contrary to the professional ethics of doctors and surgeons to claim exclusive rights to their discoveries or innovations.⁵² Also, while the infringement of patented devices or drugs can be easily detected by the presence of the infringing product, the enforcement of patents for medical procedures is much more difficult.⁵³

In the past, it has been necessary to locate and sue each infringer individually.⁵⁴ In the future, with the advent of large health care organizations with computerized databases of patient information, enforcement of such procedure patents will be easier.⁵⁵ As market pressures and the increasing dominance of large Health Maintenance Organizations reduce income for physicians, patent holders are more likely to consider the potential for profit from their discoveries.⁵⁶

Examples of recent patent applications filed on medical and surgical techniques include a method for immobilizing a patient's arms overhead in a prone position during a medical procedure,⁵⁷ a method for performing a percutaneous medical procedure without a trocar,⁵⁸ and a method and apparatus for delivering a stable gas mixture to a patient.⁵⁹ The scope of such procedure patents is further illustrated by a patent issued for a procedure and balloon catheter system for enlarging the cross-sectional area of a fluid flow passageway⁶⁰ and a procedure and device wherein a fiber optic bundle is used to remotely

BNAPTD File [hereinafter *Bill Would Limit Issuance*].

50. Reid G. Adler & Kate H. Murashige, *Biomedical Product Patent Protection Essential to High-Tech Economy*, LEGAL BACKGROUNDER, Feb. 2, 1996, available in LEXIS, News Library, WLF File.

51. *Id.*

52. William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 263-65 (1990).

53. *Id.*

54. *Id.*

55. *Id.*

56. Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties from Method Patent Stirs Debate*, 33 AM. MED. NEWS 3 (1994) [hereinafter *Just Reward*].

57. U.S. Pat. No. 5,410,769.

58. U.S. Pat. No. 5,383,886.

59. U.S. Pat. No. 5,335,653.

60. U.S. Pat. No. 5,180,367.

view the operative end of a catheter.⁶¹ The subject matter of medical and surgical procedure patents covers a broad range of topics including using ultrasound to determine the sex of a fetus, treating impotence, combining drugs and vitamins to treat cancer, treating pain, suturing internal organs, grafting skin, as well as diagnosing and treating heart problems.⁶²

As summarized above, it is clear that inventions based on medical or surgical procedures can meet the basic criteria of patentability and the PTO is now routinely issuing patents on such inventions. What is not yet clear is how strenuously the patents will be enforced and whether the courts will uphold the presumption of validity awarded by the PTO. Procedures require varying amounts of investment in terms of time and resources to be developed. The tests applied by the PTO only indirectly consider this fact in awarding a patent.⁶³ A new technique which requires little or no investment may be patentable if it meets the statutory criteria. In contrast, a complex new technique which required significant investment may be seen as either not novel or obvious and its patentability may be denied by the PTO. Legislation to amend the patent statutes may not be the answer, but clearly the awareness of these issues and a standard policy by the PTO is needed to guide the development of new medical and surgical procedures.

IV. MEDICAL AND SURGICAL PROCEDURES PATENTS IN OTHER COUNTRIES

Approximately eighty countries do not allow medical method patents.⁶⁴ Under the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement (NAFTA), member countries may exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."⁶⁵ The clear trend in many foreign countries including Canada

61. U.S. Pat. No. 4,945,895.

62. Greg Borzo, *Method Patent Fails; Court: Surgeon Doesn't Have to Pay Royalties*, 39 AM. MED. NEWS, Apr. 15, 1996, at 1.

63. See, e.g., *Panduit Corp. v. Dennison Mfg.*, 810 F.2d 1561, 1564 (Fed. Cir. 1987) (where in an infringement action by a manufacturer of plastic cable ties, the CAFC held a finding of nonobviousness was supported by the patentee's investment of seven years and millions of dollars in order to develop a successful product).

64. Reginald W. Rhein, Jr., *BIO, AMA Clash over Bill to Shield Health Pros from Suits Over Procedures*, BIOTECHNOLOGY NEWSWATCH, Nov. 20, 1995 (quoting H. Dunbar Hoskins, Jr., executive vice president of the American Academy of Ophthalmology).

65. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agree-

and Great Britain is to ban patenting of medical processes,⁶⁶ and the European Community is moving towards an absolute prohibition of medical process patents.⁶⁷

V. CURRENT LEGISLATION REGARDING MEDICAL PROCEDURE PATENTS

A July 24, 1996 spending bill⁶⁸ approved by the House included an amendment which would prohibit the PTO from using any funds to issue patents on medical procedures.⁶⁹ The amendment was similar to the House version of the Medical Procedures Innovation and Affordability Act (H.R. 1127)⁷⁰ which was recently debated. However, the amendment included exemptions for processes that are part of a patentable product and new indications for nonpatentable drugs and biologic products such as gene therapy whose effect was not previously known or obvious. Representatives of the biotechnology and pharmaceutical industries were extremely concerned that the interpretive uncertainty of the amendment could deter vital medical research.⁷¹ The amendment was part of an appropriations bill, and therefore, it is valid for only one year.⁷² On September 30, 1996, President Clinton signed into law an appropriations bill which included a provision changing the law relative to medical procedure

ment], Annex 1C, Legal Instruments — RESULTS OF THE URAGUAY ROUND vol. 31; 33 I.L.M. 81, 83-111 (1994) [hereinafter TRIPS Agreement]; see also Canada — Mexico — United States: North American Free Trade Agreement, done at Washington on Dec. 8 and 17, 1992, at Ottawa on Dec. 11 and 17, 1992, and at Mexico City on Dec. 14 and 17, 1992, art. 1709, § 3(a), 32 I.L.M., 605, 673.

66. See United Kingdom Patents Act, 1977, Part I, § 1(1)(c) (Eng.) and Canada Patent Act, R.S.C. ch. P-4, § 2 (1985) (Can.).

67. The European Patent Convention expressly excludes from patentability "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body." European Patent Convention, Oct. 5, 1973, art. 52(4), 1 B.D.I.E.L. 986, as amended by Decision of the Administrative Council of the European Patent Organization Dec. 21, 1978.

68. *House Adopts Rep. Ganske's Amendment on Funds for Medical Procedure Patents*, BNA PAT., TRADEMARK & COPYRIGHT L. DAILY, July 26, 1996 (the bill (H.R. 3814) was a spending bill for departments of Commerce, Justice and State and was approved 246-149 by the House).

69. Charles Craig, *Biotech Backers Fear Medical Patent Ban will Hurt Industry*, BIOWORLD TODAY, July 26, 1996.

70. See *infra* Part V.

71. Craig, *supra* note 69.

72. *House Adopts Rep. Ganske's Amendment on Funds for Medical Procedure Patents*, *supra* note 68 (a representative of the PTO's Office of Legislative and International Affairs stated that the amendment would not amend the Patent Act so inventors can continue to file applications on medical processes, however, the PTO is not clear on what to do with them at this point).

patents. The bill reflects a compromise between industry representatives and the various groups which support a ban on medical procedure patents.⁷³ The medical procedures revision creates a new subsection [c] to 35 U.S.C. § 287 whereby a patent owner is unable to collect damages from a "medical practitioner" who performs a "medical activity."⁷⁴

The original Senate and House bills — S. 1334, H.R. 1127 — were aimed at eliminating patent protection for medical procedures, and are believed by some members of the medical and legal communities to be contrary to the patent system's purpose which is to induce those with medical training to research and develop products.⁷⁵ Bill opponents included the American Bar Association (ABA), members of the biotechnology and pharmaceutical industries, the PTO,⁷⁶ the Pharmaceutical Research and Manufacturers of America (PhRMA),⁷⁷ and numerous patent attorneys.⁷⁸

Others believe legislation is necessary to preserve the free exchange of information that is at the foundation of current medical practice⁷⁹ and support some type of legislation to either ban or control issuance of medical and surgical procedure patents. Those who support legislation to ban medical and surgical procedure patents include the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, the American Urological Association, the Association of American Medical Colleges, and the American Medical Association (AMA).⁸⁰

73. See General Provisions of the *Defense Appropriations Conference Report*, 1996, H.R. 3610, Title VI, § 616.

74. In the revised version of 35 U.S.C § 287(2)(A), a "medical activity" is defined as "the performance of a medical or surgical procedure on a body," but excludes (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, or (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent. However, 35 U.S.C § 287(2)(F) limits this by stating that remedies would still be available where the claim of a patented use of a composition of matter contributes to the novelty. See also BNA PAT., TRADEMARK & COPYRIGHT L. DAILY, Oct. 7, 1996 (stating that a conference summary explains that such uses include novel uses of drugs, novel uses of chemical or biological reagents for diagnostic purposes, novel methods of combining drug therapies and novel methods of providing genetic or other biological therapies to a patient such as gene therapy).

75. *Agency Opposes Bills*, *supra* note 3.

76. *Do Patents Belong in Traditional Medicine?; Congress Considering Bills that Eliminate Protection*, LEGAL INTELLIGENCER, Nov. 2, 1995; see also *infra* Part IX.

77. Craig, *supra* note 69.

78. Adler and Murashige, *supra* note 50.

79. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

80. *Do Patents Belong*, *supra* note 2.

The House version of the Medical Procedures Innovation and Affordability Act (H.R. 1127) would have banned the PTO from granting patent protection for any "invention or discovery of a technique, method or process for performing a medical or surgical procedure, administering a surgical or medical therapy, or making a medical diagnosis."⁸¹ The bill contained an exception for when such techniques are performed as a necessary component of a patentable medical device or machine wherein the patent claims the technique, method, or process.⁸²

The Senate version of the Medical Procedures Innovation and Affordability Act (S. 1334) would have created an exemption from liability for patients, physicians, other licensed health care practitioners, and any health care entity with which such personnel are affiliated.⁸³ The exclusion would have covered use of, or inducement to use, "patent[ed] technique[s], method[s] or process[es] for performing surgical or medical procedure[s], administering a surgical or medical therapy, or making a medical diagnosis."⁸⁴ It would not have impacted those who make or sell pharmaceuticals or medical devices which are regulated by the Food and Drug Administration.⁸⁵ The operations of the PTO would not have been impacted by S. 1334 because it applied to enforcement of patents rather than issuance.

Heated testimony was presented at hearings before the Subcommittee on Courts and Intellectual Property of the House Judiciary Committee, where opponents of H.R. 1127 testified that the bill would interfere with the essence of protection needed for continued sponsorship of research and development.⁸⁶ G. Lee Skillington, PTO Counsel for Legislative and International Affairs, represented the view of his organization, stating that H.R. 1127 was not the proper way to address the concerns of its proponents and proposed that the PTO conduct hearings to create an administrative solution to the problem.⁸⁷

Dr. Greg Ganske, sponsor of H.R. 1127, spoke in support of

81. Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1995).

82. *Id.*

83. *Id.*

84. *Id.*

85. *Agency Opposes Bills*, *supra* note 3.

86. *Hearings*, *supra* note 4 (testimony of Dr. Frank Baldino, Jr., President and CEO of Cephalon Inc.).

87. *Hearings*, *supra* note 4 (testimony of G. Lee Skillington, Counsel with the Office of Legislative and International Affairs of the Patent and Trademark Office).

legislation to eliminate medical procedure patents, and expounded upon the medical tradition of sharing information and techniques for the public benefit.⁸⁸ His testimony emphasized that there is no need to allow patents on medical and surgical procedures. The absence of high costs for developing or testing such methods and the lack of manufacturing and regulatory costs are in contrast to the huge costs which justify patents for other types of inventions such as new medical devices and drugs.⁸⁹ Ganske added that physicians may be reluctant to share medical information for fear of allegations of patent infringement or inducement of infringement. This reluctance is a major concern of proponents of the legislation⁹⁰ because they believe the trend towards extensive patenting of medical procedures will result in reduced availability of new treatments for patients.⁹¹ These fears are well founded if patent holders, such as Dr. Pallin, prevail in their infringement suits.⁹²

Speaking in favor of H.R. 1127, Charles Kelman, M.D., President of the American Society of Cataract and Refractive Surgery, testified that "the intentional withholding of new skills and techniques for personal gain is unhealthy for patients, inhibits medical progress, and is inconsistent with the Hippocratic Oath."⁹³ Dr. Kelman further stated that new medical procedures are the result of the exchange of information between physicians regarding new techniques or variations of existing ones.⁹⁴ Kelman alleges that patents, such as Pallin's for a frown-style incision used in cataract surgery to make self-healing wounds, represent refinements of existing procedures and should not meet the requirements of a patentable invention.⁹⁵ It has been argued that Congress must act in this area because courts have been deferential to Congressional policy relative to patent issues.⁹⁶

Those who support a ban urge that the time needed to investigate ownership of a *new* procedure, the fear of allegations of patent

88. *Hearings, supra* note 4 (testimony of Dr. Greg Ganske, surgeon and Congressman (R-Iowa)).

89. *Id.*

90. *Agency Opposes Bills, supra* note 3.

91. Rhein, *supra* note 64, at 35.

92. *See infra* Part VI.

93. *Hearings, supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

94. *Id.*

95. *Id.*; *see also supra* Part II.

96. Gregory F. Burch, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1162 (1987).

infringement, and the tendency to file patents in order to protect one's interests can only detract from rapid dissemination of new ideas. In support of this position, the Director of Georgetown University Bioethics Center, LeRoy Walters, stated that "had the kidney transplantation or cardiac catheterization been patented as procedures, it seems likely that their diffusion into the clinical context would have been delayed and patient costs increased."⁹⁷

Some organizations favored one version of the bill over the other. For example, the Medical Procedure Patent Coalition⁹⁸ favored the Senate version of the bill because it allowed the PTO to continue to issue patents on medical and surgical procedures without limitations and thereby ensured that the availability, quality, and affordability of medical and surgical procedures would not be compromised. Under the Senate bill, pharmaceutical companies, device manufacturers, and biotechnology companies could continue to enforce their rights against commercial entities that infringed or induced infringement of their patents.⁹⁹ The Senate version of the bill attempted to gain the biotechnology industry's support by allowing enforcement of some patent claims for medical techniques.¹⁰⁰

Speaking for one of the numerous groups which did not support either version of the bill, Donald R. Dunner, Chairman of the Intellectual Property Law Section of the American Bar Association, testified that the goal of the patent system is to provide incentives for innovation for "any and all subject matter."¹⁰¹ Dunner further testified that it would be unfair to single out any area of subject matter and deny rewards for creativity in that area.¹⁰² He explained that the fact that the U.S. patent system has been instituted with statutory guidelines reflects a national policy that the benefit of patenting outweighs the costs.¹⁰³ Dunner further argued that the patent system promotes

97. *Embryo Transfer Technique Patent Questioned by Rep. Gore; House Subcommittee Should Review Generic Issue of Medical Process Patents, Ethicist Says*, 27 BLUE SHEET 34, at 4-5 (1987) [hereinafter *Embryo*].

98. See *infra* note 126.

99. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

100. Rhein, *supra* note 64.

101. *Hearings*, *supra* note 4 (testimony of Donald R. Dunner, ABA Chairman of the Intellectual Property Law Section); see also *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980), (where the Supreme Court stated that "The Congress intended that statutory subject matter to include anything under the sun that is made by man.").

102. *Hearings*, *supra* note 4 (testimony of Donald R. Dunner, ABA Chairman of the Intellectual Property Law Section).

103. *Id.*

dissemination of information,¹⁰⁴ which contradicts the view of supporters of the ban on medical and surgical procedure patents.

Proponents of a ban on medical process patents are also concerned that a patent examiner's seal of approval on a medical procedure patent may be misinterpreted by the general public as approval by highly trained medical experts.¹⁰⁵ In contrast, those in favor of awarding medical procedure patents feel that the PTO is fully qualified to critically evaluate and award patents for medical or surgical procedures when appropriate, even in the absence of any specialized training in the field.¹⁰⁶

In addition, some lawyers and doctors argue that the trend towards managed care in the health care industry will make it easier to collect royalties derived from patent licenses.¹⁰⁷ Also, physician resistance to patenting may decrease or physicians may have no choice given the trend towards administration of health care by large corporations who will dictate policies to protect their interests.

The Senate bill was more reasonable than the House version, because it exempted physicians, patients, and other licensed health care professionals and entities from liability for infringement from using patented medical processes. However, interpretive difficulty could raise issues as to who would qualify as a "patient, physician, or other licensed healthcare practitioner, or any health care entity with which a physician or licensed health care practitioner is professionally affiliated."¹⁰⁸ Arguably, it is not fair to allow a patent to be enforced for some applications and not others. The Biotechnology Industry Organization (BIO) still opposes the legislation because of the potential impact on acquisition or enforcement of patents for biotechnology inventions, which may be limited based on interpretation of the language of the statute once enacted.¹⁰⁹

If medical and surgical procedure patents become common because a legislative ban is not implemented and patentees are success-

104. *Id.* See also *infra* Part VIII.

105. *ASCRS Files Complaints Over Deceptive Advertisements by Samuel Pallin, MD Regarding Invention of Surgery*, PR NEWswire, May 24, 1996, available in LEXIS-NEXIS, NEWS Library, PRNEWS File.

106. *Hearings*, *supra* note 4 (testimony of Donald R. Dunner, ABA Chairman of the Intellectual Property Law Section).

107. McCormick, *supra* note 56 (quoting James Longacre, counsel for Dr. Pallin).

108. Medical Procedures Innovation and Affordability Act, S. 1334, 104th Cong. (1995).

109. *Id.* (citing Chuck Ludlam, BIO's vice-president for government relations); see also Michelle L. Robinson, *House Passes Biotechnology Patent Process Bill, Action of Other Bills Pending*, BIOWORLD TODAY, Oct. 19, 1995, at 6.

ful in infringement actions, there will be an effect on incremental improvements in techniques as well. The incentive will be to file patents on any improvement potentially eligible for patent protection, thereby changing the way medical practitioners interact in the regular course of their business. Physicians who have no interest in protecting their own proprietary rights will run up against the intellectual property system when they try to gain access to other medical or surgical techniques. Physicians, personally, may not fear infringement allegations or support patenting of medical or surgical procedures. However, as large health maintenance organizations increase their control of medical care, they will likely be dictating policies not only requiring physician employees to patent their own techniques, but also to not use those of others. Under a system where patents for medical and surgical procedures are freely allowed and enforced, even unjustified fears of infringement suits, will engender uncertainty and reluctance to employ techniques possibly *owned* by someone else.

If a patent owner prevails in an infringement lawsuit and collects damages, it will fuel the building concern on the part of health-care practitioners that payment of damages for patent infringement is a real possibility which must be factored into any decision to use a new technique. Physicians may make a preemptive decision and shy away from techniques which they believe *belong* to another physician or health care organization rather than risk the possibility of a lawsuit. In addition, if a patent owner prevails in an infringement lawsuit, large health care organizations, who employ the majority of physicians in the United States, will also become concerned about potential litigation and instruct their physician employees to behave cautiously when trying new procedures. Although this would *chill* the implementation of a procedure such as a new life saving technique, it would have a far greater impact on improvements to existing procedures. A physician would almost certainly risk a patent infringement suit to save the life of a patient. However, the potential for an impact on life saving innovations does exist if a ban on medical process patents is implemented. In either case, if a legislative ban is put in place, dissemination of new techniques and ideas will be delayed while the ownership of rights to various methods is resolved.

VI. LAWSUITS INVOLVING MEDICAL PROCEDURE PATENTS

The issue of medical and surgical procedure patents has been brought to the forefront by a patent infringement lawsuit involving a widely used technique for cataract surgery which utilizes a special

incision and no sutures. Dr. Samuel Pallin filed a lawsuit against Dr. Jack Singer alleging that Singer not only used his patented incision for cataract surgery,¹¹⁰ but induced others to infringe the patent by publishing medical journal articles about the surgical technique and instructing others in how to use the procedure.¹¹¹ This is believed to be the first case in which one physician has sued another for patent infringement involving a surgical procedure.¹¹² Dr. Singer feels that to avoid such lawsuits, other medical practitioners must withhold new and useful methods rather than freely exchange them with colleagues and/or conduct regular patent searches and file patent applications prior to sharing ideas.¹¹³ Dr. Singer is also of the opinion that mandatory disclosure in patent applications, even as early as six months after the filing date, would delay the use and improvement of new medical procedures.¹¹⁴ Opponents of proprietary rights to medical procedures claim that prior to issuance of a patent (which may take several years), it is in the patentee's interest to keep the invention secret.¹¹⁵ A proposed rule that patents be published 18 months after filing¹¹⁶ will, if enacted, partially alleviate this concern because earlier publication will be a part of the patenting process.

Dr. Pallin defended the patent in response to the complaints of fellow ophthalmologists, who had been critical of him for claiming ownership of the surgical procedure which he patented. Pallin claims that he turned to the PTO because he was denied the opportunity to publish his findings in a traditional medical journal.¹¹⁷ However, Dr. George Lundberg, Editor of the Journal of the American Medical Association said he could not imagine that given the thousands of peer-reviewed journals in existence that a researcher could not find an outlet for his work.¹¹⁸ With estimates that as many as half of all cata-

110. U.S. Pat. No. 5,080,111; *see also supra* Part I.

111. *Pallin v. Singer*, No. 93-202, 1995 U.S. Dist. LEXIS 20824 (D. Vt. May 1, 1995); *see also Hearings, supra* note 4 (testimony of Dr. Jack Singer, ophthalmologist from Dartmouth-Hitchcock Medical Center, Randolph, Vermont).

112. Lee Bowman, *Physicians Stake Claims to their Art of Healing; Courts will rule on Patents, While Medical Societies Denounce Them as Unethical, Harmful*, S.F. EXAM., July 16, 1995, at B-1.

113. *Hearings, supra* note 4 (testimony of Dr. Jack Singer, ophthalmologist from Dartmouth-Hitchcock Medical Center, Randolph, Vermont).

114. *Id.*

115. McCormick, *supra* note 56.

116. *See* H.R. 1733, 104th Cong. (1995).

117. *Hearings, supra* note 4 (testimony of Samuel Lear Pallin, M.D., Medical Director Lear Eye Clinic, Scottsdale, Arizona).

118. McCormick, *supra* note 56.

ract procedures employ Dr. Pallin's technique, potential earnings from licensing fees could be substantial.¹¹⁹ Pallin expressed a frequently argued position that based on the Constitutional basis for patent protection,¹²⁰ supporters of legislation to ban medical procedure patents are making an artificial distinction between medical procedures and devices.¹²¹

Pallin's view mirrors that of many who oppose any controls on issuance or enforcement of medical or surgical procedure patents. He claims the historical reluctance to enforce medical procedure patents against doctors is based on practical enforcement issues, not ethical concerns.¹²² He also presented the argument that royalties and licensing fees are a powerful incentive in a capitalist system and can only motivate doctors to develop new, innovative techniques, stating that doctors would not refrain from using the "best" technique available because of greater costs.¹²³

Dr. Pallin's approach implies that the increased cost to the patient as the result of royalty payments on a patent is not a factor in the debate over whether Congress should intervene and limit patenting of surgical procedures. Given the current economic pressures on the medical community and the trend towards cost containment in the health care industry, this argument has limited merit.¹²⁴

A federal district judge issued a consent order in the case invalidating all of Dr. Pallin's claims of ownership of the procedure for

119. McCormick, *supra* note 56; see also Stodghill, *supra* note 8 (stating that Pallin is trying to collect royalties of \$5 per operation from approximately 2000 eye surgeons who perform an estimated 500,000 procedures per year).

120. *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470 (1974) (explaining that patent laws "promote the progress of science and useful arts" by offering a right to exclude others from an invention for a limited period of time as an incentive to risk the costs of research and development and associated investment of time needed to develop an invention).

121. *Hearings*, *supra* note 4 (testimony of Samuel Lear Pallin, M.D., Medical Director Lear Eye Clinic, Scottsdale, Arizona).

122. *Hearings*, *supra* note 4 (testimony of Samuel Lear Pallin, M.D., Medical Director Lear Eye Clinic, Scottsdale, Arizona, stating that recent advances in computerized record keeping has eliminated the practical problem of tracking use of medical procedures in order to determine royalties).

123. *Hearings*, *supra* note 4 (testimony of Samuel Lear Pallin, M.D., Medical Director Lear Eye Clinic, Scottsdale, Arizona).

124. Of course, the argument can be made against the patenting of any invention for which the cost increases associated with exclusivity suggest limiting the protection. However, patent protection for diagnostic and therapeutic procedures are unique in that the consumer — the patient — usually has the purchasing decision made for them by either their physician or the physician's employer. This separation of purchaser and consumer makes the patient particularly vulnerable to not being treated with procedures which they would have purchased for themselves, because of cost.

sutureless cataract surgery. Pallin had demanded that Singer pay a royalty ranging from \$2,500-\$10,000 per year.¹²⁵ The case was dismissed with prejudice and Dr. Pallin was enjoined from enforcing any of the claims of the patent against anyone else in the future.¹²⁶

Hearings were recently conducted before the PTO in order to determine if the issues regarding medical procedure patents could be solved administratively as opposed to legislatively.¹²⁷ A representative of the Medical Procedure Patent Coalition¹²⁸ testified that the PTO's prior art, even for published materials, is deficient, citing the Pallin case as an example of a situation where the PTO should not have issued the patent and would not have done so had it been aware of the relevant prior art. Dr. Pallin did not bring the relevant prior art to the attention of the PTO, and none of it was published, so the PTO could not have been expected to be aware of it. In addition, the technique Pallin patented was the sum of many years of incremental improvement in a technique, and his contribution may have included only one step in the procedure which required no capital investment. The PTO is not equipped to gain access or properly evaluate the prior art, given the specialization of current medical practice.¹²⁹

Prior art for medical and surgical procedural inventions is frequently the exchange of information in operating rooms, at medical schools, in conferences or seminars, and in publications in peer-reviewed journals. This makes the examination of medical and surgical procedure patents unusually difficult for the PTO. The issue of prior art for medical and surgical procedural inventions arises in the context of re-examination of patents as well.¹³⁰ At recent hearings before the PTO, it was suggested that the PTO could expand its li-

125. Michelle L. Robinson, *Lawsuit Claiming Medical Procedure Patent Ruled Invalid*, BIOWORLD TODAY, April 15, 1996.

126. The basis of the decision was the presentation of overwhelming evidence that other physicians had used Dr. Pallin's allegedly "unique" technique prior to the date Dr. Pallin had claimed to invent it. *Id.* See generally 35 U.S.C. § 102 (1988) (requiring novelty to obtain a patent).

127. *Public Hearing on Patent Protection for Therapeutic and Diagnostic Methods*, U.S. DEPT. OF COMM. PAT. AND TRADEMARK OFFICE, May 2, 1996 (visited Feb. 16, 1997) <<http://www.uspto.gov/web/offices/com/sol/notices/diaghear.txt>>.

128. The Coalition consists of 17 medical societies and associations led by the American Society of Cataract and Refractive Surgery, and includes the AMA.

129. *Public Hearing on Patent Protection for Therapeutic and Diagnostic Methods*, *supra* note 127.

130. Re-examination is a consideration of patent validity, where anyone may request that new prior art in the form of patents or printed publications be considered in a re-evaluation of patentability of an issued patent. The types of prior art relevant to medical procedure patents will not come up in the context of a re-examination.

braries to include more scientific journals and get access to videos which have become the standard way of teaching medical and surgical techniques.¹³¹

A number of other lawsuits for patent infringement involving medical procedures are imminent. For example, notice was issued by Dr. John D. Stephens, a California physician who informed various radiologists that he plans to file suit for infringement of his 1991 patent on an ultrasound procedure which can be used to determine the gender of a fetus.¹³² Public statements of intent to enforce his patent have been made by the physician who developed the technique known as "Surrogate Embryo Transfer."¹³³ A privately held Chicago-based company, Fertility & Genetics Research funded the development of Surrogate Embryo Transfer which was the outcome of the work of a team led by Dr. John E. Buster at the University of California at Los Angeles.¹³⁴ Men's Health Resources, Inc., a group of urologists who purchased the rights to Dr. Alvaro Latorre's patented treatment for impotence have threatened hundreds of individual doctors with litigation if they do not pay a \$350 per year licensing fee.¹³⁵ Also, Yale University has recently confirmed its intention to enforce a recently issued patent for a method of detecting of breast cancer tumors by evaluating the presence of Tamoxifen metabolites.¹³⁶

The Pallin lawsuit has energized the debate over medical and surgical procedure patents. Supporters of the legislation argue that the consent order supports the need for a ban on medical procedure patents and others, such as the biotechnology industry, claim the outcome of the lawsuit reaffirms the right to patent any medical breakthrough.¹³⁷

These concerns were recently voiced to the PTO by several interested groups. At hearings to explore ways to improve the quality of patents and improve the process through which they are issued,¹³⁸

131. *Public Hearing on Patent Protection for Therapeutic and Diagnostic Methods*, *supra* note 127.

132. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery); *see also* U.S. Pat. No. 4,986, 274.

133. This technique enables a woman who is infertile or has a genetic disorder to bear a child fathered by her husband. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

134. *Embryo*, *supra* note 97.

135. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery); *see also* U.S. Pat. No. 4,127,118.

136. *Bill Would Limit Issuance*, *supra* note 49; *see also* U.S. Pat. No. 5,384,260.

137. Craig, *supra* note 69.

138. *Public Hearing on Patent Protection for Therapeutic and Diagnostic Methods*, *supra*

testimony was presented by representatives of BIO, PhRMA, the Intellectual Property Section of the ABA, and the Medical Procedure Patent Coalition. In addition to raising the issues discussed in the preceding section, it was argued to the PTO that the medical community's professional standards make it distinct.¹³⁹ This is because physicians' ethical duty to share information is much stronger than the desire to keep secrets and that it is necessary to disseminate information about a possible new procedure so that relevant practitioners can review the inventions and test it.

Several groups argued that in order to preserve the integrity of the patent system, the rules for securing a patent must be the same for inventions based on medical or surgical procedures as they are for all other types of inventions.¹⁴⁰ In addition, it was noted that there has been a practical problem with patenting procedures because one cannot easily determine who really developed them.¹⁴¹ The fear was also expressed that the lack of availability of patent protection will deter those anxious to protect proprietary interests in technology from sharing their knowledge and will force them to employ alternate means such as trade secret protection.¹⁴²

The debate continues as to the need for legislative intervention. The outcome of the Pallin suit indicates that the present system is working—the judiciary will invalidate patents that should not have survived the approval process. However, it is clear that the PTO and the medical community need to make policy changes to adapt to changes in the subject matter of patent applications which are submitted. The specialization of medical processes, the need for greater access to the prior art, and the management of medicine by large corporations must be considered in such policy changes. In addition, the medical community needs to be educated about the value of patents, specifically relative to when and where they are appropriate. If this occurs and patent attorneys and agents follow the rules which require absolute disclosure of relevant prior art to the PTO, the dilemma of medical and surgical process patents should not require a legislative ban on their issue.

note 127.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

VII. ETHICAL CONCERNS SURROUNDING THE PATENTING OF MEDICAL PROCEDURES

The conflict between the present U. S. patent policy and medical ethics has created a dilemma for physicians who have an ethical duty to freely share their knowledge and skills with colleagues for the public benefit.¹⁴³ Since the time of Hippocrates, physicians have freely exchanged information¹⁴⁴ without the expectation of financial reward for advancing medical science.¹⁴⁵ Such sharing has led to early dissemination and testing of new techniques and thus rapid improvements in technology.¹⁴⁶

The United States is unique among industrialized nations in granting patents on pure methods of medical diagnosis and treatment.¹⁴⁷ Proponents of restricting patents on medical procedures emphasize that patenting such procedures interferes with the physician-patient relationship and could lead patent holders to invade patients' privacy rights while investigating allegations of patent infringement.¹⁴⁸

The American Medical Association's ethical standards preclude physicians from patenting medical procedures.¹⁴⁹ Access to optimal medical care literally affects whether people live or die. These ethical standards create the dilemma where the value of freedom to choose the best technique to help a patient must be balanced against the potential for technical advances and economic benefits based on

143. Adelman, *supra* note 4; see also *Maintaining Confidentiality*, 346 LANCET 8984, Nov. 4, 1995 (arguing that the Hippocratic Oath is unequivocal on the duty of doctors to keep secret personal information gained in the course of their practice).

144. *AMA Criticizes Patenting of Medical Procedures*, BNA HEALTH CARE DAILY, June 21, 1995 [hereinafter *AMA Criticizes*].

145. *Id.*

146. *Hearings, supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery citing *AMA ethics*: "Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. This tradition enhances patient care, leads to early evaluation of technological advances, and permits rapid dissemination of improvements throughout the medical profession").

147. *Hearings, supra* note 4 (testimony of H. Dunbar Hoskins, Junior Executive Vice-president Americana Academy of Ophthalmology who testified that Article 52 of the European Patent Convention expressly excludes from patentability methods of treating people or animals by surgery, therapy or diagnostic methods practiced on human or animals).

148. Burch, *supra* note 96, at 1139.

149. *AMA Criticizes, supra* note 144 (reviewing *The American Medical Association's Council on Ethical and Judicial Affairs Report*, June 19, 1995, which automatically becomes AMA policy and criticizing the patenting of medical procedures saying it increases costs and limits patient access to procedures elevating economic goals above those of patient health and "severely weakening the integrity" of the profession and note that 40% of the nation's 600,00 physicians are members of the AMA).

allowance of medical procedure patents.¹⁵⁰

The general public should have open access to any techniques which may solve a medical problem. Clearly, proprietary interests should not interfere with dissemination of either new life saving procedures or incremental improvements which make a medical or surgical procedure more effective. Doctors should not have to worry about a lawsuit when deciding how to treat their patients. These concerns must be considered in the debate over whether to allow medical process patents.

VIII. INCENTIVES FOR AWARDED PROPRIETARY RIGHTS TO MEDICAL PROCEDURES

Know-how encompasses the totality of unpatented knowledge utilized in the practice of medicine. It is concerned with "detailed innovation in techniques" of a practical nature that is often the "fruit of experience and trial and error."¹⁵¹ The value of know-how results from incremental improvements in the existing state of technology and not necessarily from creative activity that raises the level of the art as a whole.¹⁵² Intellectual property protection tends to eliminate conventional scientific interaction where information is freely disseminated, and therefore, conflicts with incentives provided to scientists to achieve advancements in science and medicine.¹⁵³ It can be argued that assigning proprietary rights to medical and surgical procedures contradicts the history of the medical profession where open exchange of information has occurred through scientific seminars, textbooks, journal articles, and actual demonstrations.¹⁵⁴ Historically, substantial professional rewards such as prestige and respect have come to those who have developed new medical and surgical procedures.¹⁵⁵ The current trend is to change this reward system where exchange of information occurs spontaneously and encourage physicians to file patent applications. Those who are pro-patent contend that society rewards inventors with patents because they must be motivated to exert themselves to create and the potential for obtaining a

150. Noonan, *supra* note 52, at 265.

151. Reichman, *supra* note 25, at 656, n79.

152. *Id.*

153. Aryeh S. Friedman, *Law and the Innovative Process: Preliminary Reflections*, 1986 COLUM. BUS. L. REV. 1, 7 (1986).

154. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

155. *AMA Criticizes*, *supra* note 144.

patent motivates invention.¹⁵⁶ This theory relies on the premise that inventions require labor; inventors will not invent simply for the love of it; inventors need external incentives to invent; inventions improve social welfare, and, therefore, it is worthwhile for society to provide incentives for inventors.¹⁵⁷ Economic commentators also tend to frame the purposes of the patent system in incentive-based terms.¹⁵⁸

Three justifications for patent laws which have been proposed include means to induce individual inventors to put in the effort required to produce an invention,¹⁵⁹ to induce sponsors to make the necessary investment required to develop the invention to a commercially viable form,¹⁶⁰ and to induce intellectual property owners to disclose inventions earlier than would otherwise be required.¹⁶¹ However, there is no actual evidence to suggest that the patent system is necessary to stimulate innovation in the development of medical and surgical procedures.¹⁶² If patent protection motivates doctors and scientists to exclude others from making use of research discoveries, it undermines interactions in the medical and scientific communities that traditionally advance the state of the art. The traditional climate in the medical profession—ready sharing of information and methods—promotes the interests of the community by the validation of claimed discoveries and sharing of new ideas. The trend towards patenting creates a dilemma for doctors and scientists who seek current recognition from their peers in the midst of a competitive environment. In addition, to the extent that the requirements for acquiring rights to an invention through a patent go beyond scientific norms, by mandating broader disclosure than is necessary to earn recognition in the scientific community, some inventors may choose to ignore potential patent protection in favor of secrecy. Sharing access to unique materials and knowledge is important because it not only enables other doctors and scientists to replicate and

156. Steven Cherenksy, *A Penny for Their Thoughts: Employee-Inventors, Pre-invention Assignment Agreements, Property, and Personhood*, 81 CAL. L. REV. 597, 636 (1993).

157. *Id.* See also *infra* Part IX (noting that in the context of medical techniques, those that require minimal labor are likely to be developed in the absence of incentives. However, when the new medical or surgical technique would not have been developed without a large investment of time, labor or materials, it is imperative that some incentive exist. In the majority of cases of patents filed for new medical or surgical procedures, it appears they were not the result of a large investment of time or capital).

158. Ackiron, *supra* note 35, at 149.

159. Cherenksy, *supra* note 156, at 636-37.

160. *Id.*

161. Cherenksy, *supra* note 156; see also *infra* Part IX.

162. *AMA Criticizes*, *supra* note 144.

validate the claims, but it also allows them to compete more effectively in making new discoveries.¹⁶³

Proponents of the legislation to restrict or eliminate patents on medical and surgical procedures say the incentives offered should be the traditional rewards that are available for scientific innovation.¹⁶⁴ Therefore, patents are not needed to encourage innovation of medical procedures because most are reduced to tangible form in the normal course of medical practice.¹⁶⁵ In addition, proponents of the legislation argue that patents on medical procedures will result in price increases based on royalties charged by patent holders and the costs of patent infringement lawsuits.¹⁶⁶ The development of drugs, medical devices, and biological products can be extremely expensive due to research, development, and regulatory approval costs. The promise of significant financial rewards based on availability of patents is absolutely required as an incentive for those inventions to be created.¹⁶⁷ In contrast, there is no significant monetary investment required to develop the majority of medical and surgical methods, or costly Food and Drug Administration approval prior to use of a new technique.

Another concern over patented medical and surgical procedures is that some physicians or health care organizations may choose to keep their patented invention to themselves and thereby be the exclusive provider of a particular technique, earning more that way than by collecting royalties.¹⁶⁸ However, innovation in medical practice derives from the work of others¹⁶⁹ and is generally the result of intellectual curiosity rather than the result of financial investment in research and development.¹⁷⁰ Therefore, this concern is unlikely to have a widespread impact.

In recent years, the interest and financial investment on the part of businesses has changed the focus of medical research in the academic setting to a more applied and product oriented approach. The view of the Intellectual Property Law Section of the American Bar

163. Eisenberg, *supra* note 33, at 188 n52.

164. McCormick, *supra* note 56, at 35.

165. *Do Patents Belong*, *supra* note 2; see also *Agency Opposes Bills*, *supra* note 3.

166. *Do Patents Belong*, *supra* note 2; see also *Bill Would Limit Issuance*, *supra* note 49.

167. *Hearings*, *supra* note 4 (testimony of Charles Kelman, M.D., President American Society of Cataract and Refractive Surgery).

168. McCormick, *supra* note 56.

169. Bowman, *supra* note 112 (quoting pioneer transplant surgeon, Thomas Starzl speaking for the American Academy of Surgeons who said "it never would have crossed my mind to patent a procedure because I knew I was standing on the shoulders of others").

170. *Bill Would Limit Issuance*, *supra* note 49.

Association is that patenting is commonplace in the traditional academic research setting. Arguably, in the academic setting, discussion of research results is essential to survival, and patenting and research occur in harmony in most cases.¹⁷¹ This negates the argument that patenting interferes with the process of publication or dissemination of scientific information.¹⁷² Scientists in other fields tolerate the effect of patents as part of the process of research and development. Therefore, singling out medical processes on that basis is questionable.¹⁷³

Not all medical organizations oppose the issuance of patents. Cedars-Sinai Hospital in Los Angeles adopted a patent policy in 1982 which has resulted in a number of patents and pending applications on medical products and procedures.¹⁷⁴ The policy has made those procedures and products available to the medical community and has generated significant revenue for the hospital and its researchers.¹⁷⁵ Where research and development are needed to devise and implement a procedure and where government investment fails to adequately support research, the availability of patents can motivate investment in health care by venture capitalists.¹⁷⁶ Health maintenance organizations, clinics, and research institutions generate income through licensing and royalty agreements which can only lead to economic benefits for the medical profession in cases where preliminary investment of capital is needed.¹⁷⁷

An example supporting the case for medical procedure patents is the balloon catheter developed at Cedars-Sinai hospital. The device was described in a publication but not patented and although it was completely operational, it did not become widely available until patents were filed on improvements of the device.¹⁷⁸ This example is contrary to the widely held notion that publication promotes dissemination of scientific information and patenting delays it.

Patent law supposedly promotes investment in innovation by ex-

171. *Hearings, supra* note 4 (testimony of Donald R. Dunner, ABA Chairman of the Intellectual Property Law Section).

172. *Id.*; see also Burch, *supra* note 96, at 1160.

173. *Hearings, supra* note 4 (testimony of Donald R. Dunner, ABA Chairman of the Intellectual Property Law Section).

174. *Do Patents Belong, supra* note 2.

175. *Id.*

176. Bowman, *supra* note 112.

177. *Do Patents Belong, supra* note 2.

178. A. Bloomberg, et al., *Patenting Medical Technology: "To Promote the Progress of Science and Useful Arts,"* 317 *NEW ENG. J. MED.* 565, 567 (1987).

cluding others from financially benefiting from another's work. Those who support this view believe competition is both a cause and an effect of new and improved products and services as well as increased efficiency in productive processes. Competition motivates investment in research; the more competitive the industry, the greater the incentive.¹⁷⁹ Therefore, investment in research increases competition, because the successful innovator gains a competitive advantage over others in the same field who must develop innovations of their own if they are to stay competitive.¹⁸⁰

When a new procedure is developed which would not be developed without the availability of patent protection, the economic benefits of a patent monopoly outweigh the costs.¹⁸¹ Accordingly, the value of such a patent on a medical procedure is a function of the cost and demand for that method. If the development costs of a new technique are low, the justification for a patent monopoly is weak, regardless of how frequently the procedure is used.¹⁸² However, a valuable procedure with high research and development costs supports the case of patentability even if the procedure is not frequently used.¹⁸³ The economic incentives must be balanced with the social need to make new and helpful methods widely available and to foster the open sharing of new technology.

In some cases, medical procedure patents will result in increased dissemination of the information necessary to optimally treat patients based on the detailed disclosure encompassed in the patent application.¹⁸⁴ In other situations, the opposite will be true. Certain treatments would not be developed absent the incentive of patent protection.¹⁸⁵ Patient privacy and physician autonomy must be subordinate in importance to the availability of improved health care.¹⁸⁶ Some innovations in medical technology will be economically justified or will be the result of observations made without extraordinary effort, and therefore, be created without the incentive of patent protection. This category of innovations, which encompasses the majority of medical procedures, are usually inexpensive to create.¹⁸⁷ Rewarding

179. Eisenberg, *supra* note 33, at 218.

180. *Id.*

181. Burch, *supra* note 96, at 1161.

182. *Id.*

183. *Id.*

184. 35 U.S.C. § 112 (1988) (requiring description of the invention).

185. *Id.* at 1162.

186. *Id.*

187. Ackiron, *supra* note 35, at 150.

invention with proprietary rights is economically justified only when the improvement over the existing state of the art would not have taken place without the patent protection.¹⁸⁸

Basic research will still occur in the absence of the ability to patent medical processes. However, in cases where the process leads to a new device or drug, a ban on the process patent could result in those inventions never being pursued. This would block the maturation of such inventions to a practical and innovative device or drug, thereby denying the public access to a solution to a medical problem.¹⁸⁹ Congress cannot propose an absolute prohibition of medical process patents without presenting some manner other than private investment for such research to be funded or society will lose the benefit of medical advances.

IX. POTENTIAL IMPACT ON THE BIOTECHNOLOGY INDUSTRY

Biotechnology, often referred to as genetic engineering, or recombinant DNA research is an area of medically relevant research that is moving at a rapid pace. This research has already led to the creation of new products with medical applications such as biopharmaceuticals and genetic screening tests.¹⁹⁰ From 1981 to March of 1995, the FDA had granted approval to sixteen biopharmaceutical products, including fifteen therapeutics and a vaccine. Overall sales are expected to grow at an average of twelve percent per year to almost \$16 billion by 2004.¹⁹¹ Investment in biological research has yielded an abundance of discoveries. Although few of these products are presently available to consumers, some are beginning to reach the marketplace, and more are on the way. This trend suggests that the biotechnology industry is coming of age. The enormous costs for research and development in biotechnology and the need for long lead times to recoup the costs of research endeavors has made intellectual property protections all the more essential for the United States to maintain a competitive position in the global marketplace.¹⁹² Industry leaders are extremely concerned about the potential impact of a ban on medical procedure patents.¹⁹³ Specifically, the concerns of

188. *Id.*

189. Adler & Murashige, *supra* note 50.

190. Reichman, *supra* note 25, at 643.

191. Roger E. Shamel & Michael Keough, *Sales of US Biopharmaceutical Products expected to Triple by 2004*, GENETIC ENGINEERING NEWS, March 15, 1995, at 6.

192. Noonan, *supra* note 52.

193. *Agency Opposes Bills*, *supra* note 3.

industry leaders include the uncertain effect of what is perceived as vaguely worded legislation on the issuance of patents related to gene therapy, *in vitro* diagnostics and biotechnology inventions in general.¹⁹⁴

Academic medical research centers conduct mainly basic medical and clinical research. The systematic development of new therapeutics has been relegated to private profit-oriented pharmaceutical companies which have been the source of almost all new drugs in the last twenty years.¹⁹⁵ This system relies on the pharmaceutical industry to develop the ideas which derive from basic medical research. The costs of research and development associated with new drugs or medical devices are so high that many would not be available today if the patent system did not exist.¹⁹⁶

Until legislation such as the proposed ban on medical and surgical procedure patents is enacted and interpreted through case law, it is unclear how far a ban on medical procedure patents would extend and therefore how much it would impact the biotechnology industry.¹⁹⁷ Representatives of the Biotechnology Industry Organization (BIO)¹⁹⁸ argue the risk to innovations in biotechnology is more critical than any value which may be obtained by a ban¹⁹⁹ and that the scientific and economic consequences of eliminating "new use" procedure patents could be devastating to both the pharmaceutical and biotechnology industries.²⁰⁰

Industry representatives recognize that the major advances in technology and the manner that research and development is currently conducted may require adjustments in the patent laws. The example of the sequencing of the human genome is relevant because it is generating large amounts of information, but not necessarily products. However, the information being generated will lead to patentable inventions and products at some point. This is leading companies to protect their discoveries as trade secrets rather than publishing so they are not precluded from the possibility of later

194. *House Adopts Rep. Ganske's Amendment on Funds for Medical Procedure Patents*, *supra* note 68; *see also* Craig, *supra* note 69.

195. Ackiron, *supra* note 35.

196. Bloomberg, *supra* note 173.

197. Noonan, *supra* note 52.

198. BIO represents over 580 companies, academic institutions, state biotechnology centers and related organizations.

199. *Agency Opposes Bills*, *supra* note 3.

200. Noonan, *supra* note 52.

patenting their inventions.²⁰¹

The concerns of the biotechnology and pharmaceutical industries center around the vagueness of the proposed legislation and the potential real and perceived impact on active areas of research such as gene therapy. Industry representatives legitimately fear that even an inaccurate perception that both biotechnology and pharmaceutical research and development will be impacted could hurt investment at a critical time in the evolution of the biotechnology industry.²⁰²

X. PROPOSED SOLUTIONS TO THE QUESTIONS SURROUNDING PATENTING OF MEDICAL AND SURGICAL PROCEDURES

The various options to solving the medical and surgical procedure patent dilemma include legislation such as that presented in the House and Senate bills, the recent change in the patent statute relating to damages,²⁰³ and the view that a legislative ban is inappropriate. At issue is the proper role of the PTO, the proper role of the courts, and the possibility for a requirement of compulsory licensing based on industry policy or legislative action.

The creation of the Court of Appeals for the Federal Circuit (CAFC) as a single forum for appeals in patent case is resulting in more uniform approaches to interpretation of the patent statutes. The CAFC has clearly taken the approach that patents are personal property.²⁰⁴ In parallel, the role of government has grown such that it now includes the power to regulate the use of property in accordance with what it sees as the public interests.²⁰⁵ Specific statutory exceptions to the right to a patent have been justified and therefore enacted in areas of "public interest."²⁰⁶

Examples include the inability to patent an invention useful for incorporation of atomic energy or fissionable material into a nuclear weapon.²⁰⁷ In the recent past, the courts have also acted to refine patent rights and have applied equitable doctrines in denying injunctions to patent owners. Such a denial effectively grants the alleged in-

201. Adler and Murashige, *supra* note 50.

202. *But see* 35 U.S.C. § 102(g) (1988) (barring patentability if one suppresses or conceals an invention).

203. *See Medical Procedures Innovation and Affordability Act*, H.R. 1127 104th Cong. (1995), and *Medical Procedures Innovation and Affordability Act*, S. 1334 1127 104th Cong. (1995).

204. *Smith Int'l Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577 (Fed. Cir. 1983).

205. Ackiron, *supra* note 35.

206. *Id.*

207. 42 U.S.C. § 2181 (1988).

fringer a compulsory license.²⁰⁸

A number of situations have arisen where the government requires compulsory licenses on equitable terms. When the government denies a patent because the technology relates to a weapon system, it compensates the applicant for any damages caused by a secrecy order and the government's use of the invention.²⁰⁹ The Department of Agriculture may grant compulsory licenses when needed to supply "fiber, food or feed" if the owner cannot or will not supply the public needs.²¹⁰ In addition, the Attorney General may forward a certification to a Federal District Court ordering compulsory licensing under the Clean Air Act for an invention necessary to comply with provisions of the Act when alternatives do not exist and failure to license would tend to create a monopoly.²¹¹ Finally, under the 1980 amendments to the Patent and Trademark Act intended to stimulate biomedical research, a patent applicant may be required to license an invention to the government "at will." This deems the federal government immune from injunction for use or manufacture of a patented invention, while requiring it to pay the patentee "reasonable and entire compensation" for the use thereof.²¹² However, recently the CAFC has narrowed "public policy" exceptions to the right to a patent in parallel with actions by Congress to strengthen patent rights.²¹³

XI. CONCLUSION

Asserting one's claim to a discovery is probably not in itself a serious threat to the purity or progress of science. This behavior is part of the competitive attitude that characterizes many of the fastest-moving arenas of scientific inquiry. The scientific and medical communities have historically rewarded those who make original contributions to the pool of knowledge by giving them professional recognition. Because patent law gives inventors the right to exclude others from using their discoveries even after public discussion or

208. Ackiron, *supra* note 35.

209. 35 U.S.C. §§ 181-183 (1988).

210. Plant Variety Protection Act, 7 U.S.C. § 2404 (1988).

211. Clean Air Act, 42 U.S.C. § 7608 (1988).

212. 28 U.S.C. § 1498 (1988 & Supp. IV 1992).

213. The *Orphan Drug Act*, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 15, 21, 43, and 45 U.S.C.), the *Drug Price Competition Act*, 21 U.S.C. § 355 (1988), and the *Patent Term Restoration Act* of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 321 (1988)), all indicate the support of the legislature and the judiciary that strong patent protection promotes innovation which in turn is in the best interest of the general public.

demonstration of a new method, it can upset the balance of incentives that have traditionally motivated scientific innovation. The potential severity of the chilling effect which widespread patenting will have on innovation is already apparent in patent-driven industries such as biotechnology where companies routinely have extensive controls on dissemination of "proprietary" information. This policy often delays exchange of ideas and discoveries amongst scientists. By allowing patents on medical and surgical procedures, society pays in terms of increased health care costs, delayed access to new procedures, interference with the privacy of the physician-patient relationship, and loss of medical openness which must be rationalized by a patent policy. The essential role of innovation and understanding of the motivations that lead to it are important for the progress of medical science and must be balanced against successful business strategies to insure future medical advances.

Based on the three levels of patent law — the Constitutional basis, the Congressional legislation, and the interpretive case law — new legislation should not be necessary to stem the tide of unreasonable claims to ownership of medical and surgical procedures. In the context of patent infringement suits, courts tend to analyze each invention strictly by interpretation of existing statutes and not consider the benefit of a particular invention to the general public when making a decision as to validity.²¹⁴ The fact that courts interpret the statutory law on patent validity in this mechanical manner means that in the absence of a requirement for compulsory licenses, medical procedure patents that meet the statutory criteria will lead to enforceable patents. This makes it critical that a policy be established which satisfies the PTO and the relevant groups which have expressed concern over this issue, and the policy should require compulsory licensing in order to get relevant inventions out into the general public. If policy does not work, a statutory change such as enacted relative to nuclear weapons and the Plant Variety Protection Act and the Clean Air Act will be needed. Allowing such legislation may restrict industries which exist on the periphery of the medical community and depend upon proprietary rights for survival.

In order to evaluate whether the patenting of medical and surgical techniques is appropriate, such processes may be analyzed in terms of those that require minimal investment or significant investment to develop. The techniques can be divided into two categories: one which represents an incremental change in existing technology

214. Burch, *supra* note 96, at 1150.

and one which represents a significant advance. Patent protection is appropriate where innovation requires investment for research, development, and regulatory costs. When investment is required in order to develop the new medical or surgical method, it is imperative that an incentive exists in order to attract the necessary capital.

The majority of patent applications filed for new medical or surgical procedures fall into the first category: they represent technical advances that make a procedure more effective or efficient but are not the result of a large investment of time or capital.²¹⁵ Some techniques which are incremental technical advances may not satisfy the criteria of a patentable invention based on a lack of novelty or because they would have been obvious to those with ordinary skill in the art.²¹⁶ The existing patent laws will weed out such patent applications either in the approval process or will invalidate the patent in the courts. This assumes the PTO improves the ability to do prior art searches which must encompass non-published references including video tapes of procedures (which are the most common way medical or surgical procedures are taught). The PTO should hire specialists or consultants when necessary to be sure prior art searches are complete, and the PTO must also be more effective in evaluating where patent protection is deserved. Incremental advancements in a technique should not qualify for patent protection and the best place to resolve disputes as to the significance of an "invention" is in the PTO approval process. If inventions which are not deserving of patent protection are awarded a patent, such as in the Pallin case, the courts should be able to negate the presumption of validity based on a finding of lack of novelty or obviousness in the context of an infringement action.

The need for medical procedure patents to foster innovation is not compelling in cases where minimal investment is required and the extent to which the majority of such medical or surgical techniques will require the incentive of patent protection in order to be developed cannot overcome the potential social costs and ethical issues of allowing such patents to issue and be upheld. Social costs include reduced access to such procedures due to exclusive use by the patentee or unavailability due to increased costs. There would be an impact on the open sharing of information and public discussion of new techniques such that the corresponding peer evaluation would decrease. In addition, interference with the physician-patient rela-

215. See *infra* Part VII.

216. See 35 U.S.C. § 103 (1988).

tionship by invasion of patient privacy when investigating allegations of patent infringement clearly raises ethical concerns and could not be justified for inventions that require minimal investment. However, a ban is not required because the existing system will either weed out such "inventions" or it can be modified to negate patenting when it is not appropriate without a major revision of the patent laws.

In contrast, the availability of medical and surgical procedure patents is imperative for advances that require significant investment. This creates a paradox because of the ethical and social concerns associated with allowing such patents. A complete ban on medical procedure patents may mean that a life saving technique would not be developed because research and development costs are too high to justify the expense without a patent as a financial incentive. The concern that such techniques would not be available in the absence of economic incentives gains significance as large health care organizations concerned about the bottom line take over management of patient care. They will require some incentive to be willing to invest in development of new methods. The difficulty in evaluating the impact of restrictive legislation is more critical in such cases where the social costs and ethical issues are more easily rationalized.

The damage which a ban on medical procedure patents could do to the biotechnology and pharmaceutical industries is also a key factor in determining if support for restrictive legislation is appropriate. Any new legislation will have to allow patenting to continue in those industries. If the Senate version of the Medical Procedures Innovation and Affordability Act (or something like it) is passed, one cannot predict where the courts will draw the line as to what is a pure procedure and what is a "necessary component of a patentable medical device wherein the patent claims the technique, method or process."²¹⁷ The definitions of "medical practitioner" and "medical activity" in the recently approved legislation raise similar concerns.

In any event, a patent should not be a windfall to the owner, but fair compensation to justify the business risk and pay for the inventive effort. A legislative ban is not the most effective way to accomplish that goal. An industry policy such as the compulsory licensing required by statute under the Plant Variety Protection Act,²¹⁸ the Clean Air Act,²¹⁹ and the 1980 amendments to the Patent and Trade-

217. *Medical Procedures Innovation and Affordability Act*, H.R. 1127, 104th Cong. (1995).

218. *Plant Variety Protection Act*, 7 U.S.C. § 2404 (1988).

219. *Clean Air Act*, 42 U.S.C. § 7608 (1988).

mark acts,²²⁰ could provide an incentive to innovate by fairly compensating for development costs while, at the same time, minimizing the harmful effects of exclusivity in this context.

The problem with medical process patents stems from the change in the way the medical profession is run: increasingly like a business. We cannot escape the fact that physicians and health care organizations want to own inventions and capitalize on them. Nor is it realistic to assume that they will not find a way to do so even if they cannot obtain a patent. Any change in the law or policy to deal with this problem must promote disclosure. To encourage protection of inventions as trade secrets is the worst possible outcome and could be the result of a ban on medical and surgical procedure patents. Work must be done to create a consistent well-defined PTO policy and improve access to relevant prior art. In addition, compulsory licensing should be required in cases where a technique is needed to save lives or make a procedure more effective. Any compulsory licensing must require fair compensation to the patentee. Also, the PTO must actively deter inequitable conduct—such as non-disclosure of material prior art—and encourage patent attorneys and agents to present a fair case to the PTO for effective prosecution.

Many new medical techniques will not pass the requirements of the PTO and be denied a patent. Still others will be invalidated in the court system. A combination of these two levels of control with a strong industry policy regarding promotion of access to new techniques is imperative especially where there is no existing solution to a medical problem.

220. The *Orphan Drug Act*, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 15, 21, 43, and 45 U.S.C.), the *Drug Price Competition Act*, 21 U.S.C. § 355 (1988), and the *Patent Term Restoration Act* of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 321 (1988)), all indicate the support of the legislature and the judiciary that strong patent protection promotes innovation which in turn is in the best interest of the general public.

